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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,978	07/28/2003	Olaf Ritzeler	02481.1737-01000	4099

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EXAMINER

DAVIS, ZINNA NORTHINGTON

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/627,978	Applicant(s) RITZELER ET AL.	
	Examiner Zinna Northington Davis	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-69 is/are pending in the application.
- 4a) Of the above claim(s) 52-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-41 and 51 is/are rejected.
- 7) ☒ Claim(s) 42-50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/812,785.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3/25/04</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Claims 35-69 are pending.
2. In the response filed September 24, 2004, Applicants have elected the invention of Group I, claims 35-51 with traverse. Claims 52-69 are withdrawn from consideration.
3. The issue of rejoinder will be addressed upon allowance of the claimed subject matter.
4. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Response to the Restriction/Election of Species

Applicants traverse this restriction requirement because there would be no serious burden on the Examiner to examine all Groups together. In paragraphs 3-4 of the Office Action, the Examiner explains why it is believed that the inventions are distinct. Even if the inventions were distinct, the Office Action does not provide an explanation, as required by MPEP §803, of why examination of those inventions together would create a serious burden.

It is the Examiner's position:

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- In the Office Action mailed September 7, 2004, the inventions of Groups (IV-VI) are identified as distinct.
- There is a serious burden on examining these inventions together.
- The chemical compounds are diverse in scope. The compounds differ in elements, chemical structure and chemical property. The compounds are not recognized as a general class of compounds to which a single method of treating could be attributed.
- The burden placed on the examiner is the examination of independent and patentably distinct subject matter, which could be, filed as separate patent applications.

Applicants traverse the propriety of the restriction requirement, at least claims 52-66 (Groups II and III) should be rejoined for examination once the claims of Group I are found allowable. MPEP §821.04 states that "if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined." The method claims of Groups II and III depend either directly or indirectly from claims 35 or 38 in Group I and should therefore be rejoined for examination when claims 35 and 38 are found allowable.

It is the Examiner's position:

- The examiner has required restriction between product and process claims.
- Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or

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otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

- The process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
- In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104.
- Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.
- Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*; *In re Brouwer* and 35 U.S.C. §103(b)," 1184 O.G. 86 (March 26, 1996).
- Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise

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include all the limitations of the product claims. Applicants are reminded of propriety of process of use claims in consideration of the "reach-through" format, which is drawn to mechanistic, receptor binding or enzymatic functionality. Reach through claims are considered lacking of descriptive and enabling support from the specification. Thus, rejoinable process of use claims are those with particular diseases named with efficacy support from the specification for treating a particular disease. Failure to do so may result in a loss of the right to rejoinder.

- Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP §804.01. Filing of appropriate terminal disclaimer in anticipation of a rejoinder may speed prosecution and the process of rejoinder.
- Accordingly, applicants and the Examiner affirm the election of Group I, claims 35-51 and a preferred species.

5. Claims 35-51 are Markush claims which are generic to the elected invention.

These Markush claims lack unity of invention. Accordingly, the Markush type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. See MPEP 803.02.

6. Claims 35-51 are objected on the grounds that the claims are drawn to an improper Markush group. In re Harnisch, 206 USPQ 300, states that a unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being

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essential to that utility. In the instant case, the claimed subject matter does not share a substantial structural feature disclosed as being essential to that utility.

The requirement for a proper Markush claim is that it includes only substances that in their physical, chemical and physiological characteristics are functionally equivalent. The members of the instant Markush groups possess widely different, physical and chemical properties. The compounds are not considered functionally equivalent and are so diverse that they demonstrate dissimilar and unrelated properties. The mere fact that there is structural similarity in pharmaceutical agents is not in itself reason to render all the embodiments functionally equivalent.

The improper Markush groups are B₆-B₉ and R¹-R⁸.

7. The examined subject matter is as follows:

A compound of formula I where R₁, R₅, R₆, R₇, and R₈ are H; B₆-B₉ are carbon atoms; R₂ is chlorine; R₃ is -OR¹⁰; R¹⁰ is alkyl; R₄ is -NHC(O)R¹⁵ and R¹⁵ is pyridyl. Amending the claims to the examined subject matter would overcome the improper Markush rejection.

8. The radicals within the definition of R¹-R⁸ and B₆-B₉ are independent and patentable distinct. If a search is extended to other distinct species beyond that of the elected species, the following rejections are applicable.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. Claims 35-41 and 51 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Huth et al (Reference A).

The instantly claimed compounds are disclosed. At columns 1 and 2, see compound disclosed by formula I. The compounds are effective on the central nervous system.

11. Claims 35-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by DiNinno et al (Reference B).

The instantly claimed compounds are disclosed. At column 79, see example 79. At column 92, see examples 32 and 33.

12. Claims 42-50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims to the extent that the claims read on the examined subject matter as recited above.

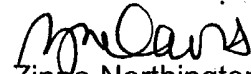
13. The Information Disclosure Statement filed July 28, 2003 have been considered. The references alone or in combination forms do not teach nor suggest the structurally similar compounds as the examined subject matter.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.

15. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

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16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.


Zinna Northington Davis
Primary Examiner
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Znd
12.21. 2004